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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------------------------------------------|-------------|-----------------------|-----------------------|------------------|
| 10/031,685 | 04/03/2002 | Patricia Anne Nuttall | 2488-1-002 | 6308 |
| 23565 | 7590 | 06/30/2004 | EXAMINER | |
| KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601 | | | BELYAVSKYI, MICHAEL A | |
| | | | ART UNIT | PAPER NUMBER |

1644

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/031,685 | Applicant(s) NUTTALL ET AL. | |
| | Examiner Michail A Belyavskyi | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction

1. Applicant's amendment, filed 01/22/02 is acknowledged.

Claims 1-39 are pending

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted:

I. Claims 1-7, 11-21, 38 and 39 are drawn to a recombinant protein that exhibit significant sequence homology with tick-derived protease inhibitor protein sequence set forth in SEQ ID NO:2, a pharmaceutical composition comprising said protein, a vaccine comprising said protein and a process for the formulation of a pharmaceutical composition comprising said protein.

II. Claims 8-13, 16-21 are drawn to a recombinant protein derived from a blood-feeding arthropod ectoparasite that inhibits tryptase and a pharmaceutical composition comprising said protein a vaccine comprising said protein and a process for the formulation of a pharmaceutical composition comprising said protein.

III. Claims 22, 31, 32 and 34 are drawn to a method of the preventing or treatment of a disease in a subject, comprising administering to said subject a pharmaceutical composition, comprising a recombinant protein that exhibit significant sequence homology with tick-derived protease inhibitor protein sequence set forth in SEQ ID NO:2

IV. Claims 22 and 34 are drawn to a method of the prevention or treatment of a disease in a subject, comprising administering to said subject a pharmaceutical composition, comprising a recombinant protein derived from a blood-feeding arthropod ectoparasite that inhibits tryptase.

V. Claims 23-27, 29 and 35 are drawn to a nucleic acid molecule encoding a recombinant protein that exhibit significant sequence homology with tick-derived protease inhibitor protein sequence set forth in SEQ ID NO:2, a vector and a host cells and a method of producing said protein.

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VI. Claims 28 is drawn to a transgenic animal that has been transformed by a nucleic acid molecule encoding a recombinant protein that exhibit significant sequence homology with tick-derived protease inhibitor protein sequence set forth in SEQ ID NO:2

VII. Claim 30 is drawn to a method for the detection or quantification of tryptase.

VIII. Claim 33 is drawn to a tryptase inhibitor.

IX. Claims 36 and 37 are drawn to a method for the depletion or removal of tryptase from a food product or a cell culture comprising contacting the food product or cell culture with a recombinant protein that exhibit significant sequence homology with tick-derived protease inhibitor protein sequence set forth in SEQ ID NO:2.

3. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

As was also found in the International Search Report, the Invention of Group I was found to have no special technical feature that defined the contribution over the prior art of Elrod,K., et al (Am J Respiratory critical Care Medicine, 1997, Vol.156, pages 375-381) or Katunuma, (NADV.Enzyme Regul. 1990, Vol.30, pages 377-392)

Elrod,K., et al, disclosed a protein (lactoferrin) that is tryptase inhibitor and can be considered as a functional equivalents of the protein having the sequence set forth in SEQ ID NO:2. Similary, Katunuma, disclosed a proteins (trypstatin and A4-inhibitor) that is tryptase inhibitor and can be considered as a functional equivalents of the protein having the sequence set forth in SEQ ID NO:2.

Since Applicant's Inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

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Species Election

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If Group VIII is elected, applicant is required to elect a specific tryptase inhibitor selected from group recited in Claim 33.

These species are distinct because their structure, physicochemical properties and mode of action are different. The examination of species would require different searches in the scientific literature.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

5. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

A telephone call was made to David Jackson on 6/16/2004 to request an oral election to the above restriction requirement, but did not result in an election being made.


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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841 .

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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June 28, 2004


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